K102621

SYBRON DENTAL SPECIALTIES

JAN 28 2011

Section III – 510(k) Summary of Safety and Effectiveness

Submitter:
Sybron Dental Specialties Inc.
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Orange, CA 92867
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Wendy Garman – Contact Person

Date Summary Prepared: September 2010

Device Name:

- Trade Name – *Solstice*
- Common Name – L.E.D. Curing Light
- Classification Name – Ultraviolet activator for polymerization, per 21 § CFR 872.6070

Devices for Which Substantial Equivalence is claimed:

- Kerr Corporation, *Demi*

Device Description:

The *Solstice* is a Light Emitting Diode (LED) visible light curing light used for the polymerization of light-cured materials by dental professionals. The *Solstice* consists of an LED curing handpiece and a charging system. The plastic molded handpiece contains an LED light engine, battery, and printed circuit board containing the electronics. A digital circuit and microprocessor will be utilized to control two (2) different curing modes (10 and 20 seconds). Each mode specifies LED curing output and audible beep timing. The *Solstice* uses a single pushbutton trigger to activate the LED curing output and select the curing mode.

Intended Use of the Device:

The intended use of the *Solstice* is for the polymerization of light-cured materials by dental professionals.

Substantial Equivalence:

The *Solstice* is substantially equivalent to one other legally marketed device in the United States. The *Solstice* functions in a manner similar to and is intended for the same use as the *Demi,* manufactured by Kerr Corporation.

The *Solstice* is similar to the *Demi* in that it is a cordless battery-operated device, uses LED as the light source, and has user-selectable curing modes. The *Solstice* differs from the *Demi* in that the *Solstice* does not utilize a light guide to direct the light from the body of the unit to the tip of the light guide, but rather the LEDs are mounted at the tip of the unit. The *Solstice* does not require a cooling fan, as demonstrated by temperature data which has been included in this submission. The *Solstice* uses a Lithium Iron Phosphate battery, as opposed to the Lithium Ion battery of the *Demi*. Unlike the *Demi*, which during use shifts light output intensity from 1100mW/cm^2 to 1300mW/cm^{2}multiple times throughout the curing cycle, the *Solstice* emits a constant light output.

Non-Clinical Test Data:

Biocompatibility studies have been conducted on a representative resin similar to the resin used to produce the handle of the *Solstice* (the only difference is the color). Included in this submission is a statement from the component manufacturer indicating that samples from typical production lots of the resin were subjected to the biocompatibility tests and passed.

This 510(K) submission also includes depth of cure testing data used to evaluate the performance of the *Solstice* compared to the predicate device. Also included is irradiance data which demonstrates light intensity and peak wavelength.

The *Solstice* software has been successfully validated to confirm the performance of the device.

Clinical Test Data:

Clinical testing has not been conducted on this product.

Conclusion:

Based upon the biocompatibility studies, similar technological/performance characteristics as compared to the predicate device, and successful validation of the *Solstice* software, the clinical performance of the *Solstice* is deemed to be substantially equivalent to the *Demi*.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Kerr Corporation
C/O Ms. Wendy Garman
Sybron Dental Specialties
1717 West Collins Avenue
Orange, California 92867

JAN 28 2011

Re: K102621
Trade/Device Name: Solstice
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator for Polymerization
Regulatory Class: II
Product Code: EBZ
Dated: January 21, 2011
Received: January 24, 2011

Dear Ms. Garman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102621

Device Name: *Solstice*

Indications for Use:
The intended use of the *Solstice* is for the polymerization of light-cured materials by dental professionals.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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